PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

Combivent® U.D.V.

solution for inhalation
(ipratropium bromide and salbutamol sulphate)

Read all of this leaflet carefully before you start using COMBIVENT U.D.V.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT COMBIVENT U.D.V. CONTAINS

- COMBIVENT U.D.V.s contain a nebuliser solution. Each 2,5 ml unit dose vial contains 3,01 mg salbutamol sulphate (equivalent to 2,5 mg salbutamol base), and 0,52 mg ipratropium bromide (equivalent to 0,5 mg ipratropium bromide anhydrous).
- The other (inactive) ingredients are: sodium chloride, 1N hydrochloric acid and purified water/water for injection.

2. WHAT COMBIVENT U.D.V. IS USED FOR

COMBIVENT U.D.V. is a nebuliser solution, and is for use with a device called a 'nebuliser'. This changes your medicine into a mist for you to breathe in.

COMBIVENT U.D.V. contains two different medicines, called ipratropium bromide and salbutamol sulphate. Both belong to a group of medicines called bronchodilators. They are used to make breathing easier in an illness called 'obstructive pulmonary disease' (wheeziness, difficulty in breathing, chronic cough). They work by opening up your airways.

3. BEFORE YOU USE COMBIVENT U.D.V.

Do not use COMBIVENT U.D.V.:

- if you are allergic (hypersensitive) to ipratropium or salbutamol or any of the other ingredients in COMBIVENT U.D.V.
- if you are allergic to similar medicines which contain atropine or medicines like atropine

- if you have a heart problem called 'hypertrophic obstructive cardiomyopathy'. This is where the wall between the two sides of the heart gets bigger and blocks the blood flow
- if you have a very fast heart beat (called 'tachyarrythmia')
- for patients younger than 12 years of age, as there is no experience of the use of COMBIVENT U.D.V. in children under 12 years

Do not use COMBIVENT U.D.V. if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using COMBIVENT U.D.V.

Take special care with COMBIVENT U.D.V.:

Check with your doctor or pharmacist before using this medicine if:

- You have glaucoma (high pressure in the eye), or have been told that you may develop it
- You have heart or circulation problems, or have had a recent heart attack
- You have diabetes (too much sugar in the blood)
- You have an over-active thyroid gland
- You have difficulty emptying your bladder (urinating)
- You are a man who has prostate problems
- You have cystic fibrosis
- You have ever had something called 'phaeochromocytoma'. This is a rare tumour of the adrenal gland. Using COMBIVENT U.D.V. can make the symptoms of this worse.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before using COMBIVENT U.D.V.

Taking COMBIVENT U.D.V. with food and drink:

COMBIVENT U.D.Vs can be used with or without food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby while using this medicine, please consult your doctor, pharmacist or other health-care professional for advice:

- if you are pregnant or planning to become pregnant, as it is not known if COMBIVENT U.D.V. will harm your unborn baby.
- if you are breastfeeding or are planning to breastfeed, as it is not known if this medicine will harm your baby.

Driving and using machinery:

COMBIVENT U.D.V. may cause symptoms such as dizziness, headache and tremor as well as problems with the eyes. You should not operate hazardous machinery, including automobiles, until you are reasonably certain that COMBIVENT U.D.V. does not affect your ability to do so safely.

Taking other medicines with COMBIVENT U.D.V.:

If you are taking other medicines on a regular basis, including prescription medicines or medicines bought over the counter, and complementary or traditional medicines, including vitamins and herbal medicines, the use of COMBIVENT U.D.V. with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health-care professional for advice.

COMBIVENT U.D.V. may affect the way other medicines work, and other medicines may affect how COMBIVENT U.D.V. works. Know the medicines you take. Keep a list of them and show it to your health-care provider and pharmacist when you get a new medicine. It is best to ask your doctor or pharmacist for advice before you start taking any other medicine.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Medicines to help your breathing (eg. theophylline) and medicines called 'beta-mimetics', such as fenoterol
- Medicines called 'anticholinergics', which can be used to treat colic pain, Parkinson's disease, problems emptying your bladder (urinating), or lack of control of your bladder or bowels
- Corticosteroid medicines such as prednisolone, cortisone
- 'Water tablets' (also called diuretics)
- Medicines called 'beta-blockers' such as propranolol. These can be used to treat heart problems, high blood pressure, anxiety or migraine
- Medicines for depression
- Digoxin, used for a fast heart beat or for heart failure

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using COMBIVENT U.D.V.

Operations:

Some gases used in operations (anaesthetic gases) may affect how your medicine works. If you are about to have surgery, make sure that you tell your doctor, dentist or anaesthetist that you are using COMBIVENT U.D.V.

4. HOW TO USE COMBIVENT U.D.V.

Use COMBIVENT U.D.V. as follows:

- Use with a suitable nebuliser or intermittent positive pressure ventilator
- Follow your health-care providers' directions carefully – always use COMBIVENT U.D.V. exactly as your doctor told you. You should check with your health-care provider or pharmacist if you are not sure.
- Do not use more or less often than recommended.

How many dose units:
The recommended dose for adults (including the elderly), and children over 12 years:
Acute attacks: Use the contents of one unit dose vial. In severe attacks if your breathing is not improved by one unit dose vial, a second one may be necessary – in this case you must contact your doctor or your nearest hospital straight away.

Maintenance treatment: Use the contents of one single dose vial, three or four times a day.

COMBIVENT U.D.V. is not recommended for children under 12 years.

Do not swallow or give COMBIVENT U.D.V. by injection.

Do not use more than your doctor has told you.
See your doctor straight away if:

- You feel your medicine is not working as well as usual
- You need to use the nebuliser more than your doctor has recommended

Your doctor may need to check how well your medicine is working, and in some cases may need to change your medicine.

How to use your nebuliser:
Read through the following numbers 1 to 6 first, before starting to use your nebuliser.

1. Get your nebuliser ready by following the manufacturer's instructions. Ask your doctor if you are not sure how to use it.

2.



- Carefully separate a new dose unit from the strip
- Do not use if it is already open or if the liquid inside is discoloured

3.



- Twist off the top
- Always hold it upright while you do this

4.



- Squeeze all the contents of the dose unit into the nebuliser chamber
- Your doctor will tell you if you need to use a different amount
- If your doctor has told you that your medicine needs to be diluted, you will be given 'sterile sodium chloride 0.9%' solution. Your doctor will tell you how to do this

5. Use your nebuliser as directed by your doctor.

6.

- After you have finished, throw away any leftover medicine carefully
- Follow the manufacturer's instructions on how to clean your nebuliser
- It is important to keep your nebuliser clean.

If any of the liquid or mist accidentally gets into your eyes you may have painful, stinging or red eyes, dilated (enlarged) pupils, blurred vision, or see colours or lights. If this happens, talk to your doctor for advice. If you get problems with your eyes at any other time, talk to your doctor for advice.

Do not share medicines prescribed for you with any other person, and do not use it to treat any other condition.

If you have the impression that the effect of COMBIVENT U.D.V. is too strong or too weak, talk to your doctor or pharmacist.

If you use more COMBIVENT U.D.V. than you should:

In the event that you have used too much COMBIVENT U.D.V. or have accidentally taken it, consult your doctor or pharmacist right away. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use COMBIVENT U.D.V.:

- If you forget a dose, use it as soon as you remember it.
- However, if it is time for the next dose, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.

If you have any further questions, ask your doctor or pharmacist.

5. POSSIBLE SIDE-EFFECTS

COMBIVENT U.D.V. can have side-effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side-effects – you may need urgent medical treatment:

- If after using COMBIVENT U.D.V., you are wheezy or have other difficulties in breathing, do not use any more (unless you have been told to by your doctor)
- Allergic reactions – the signs may include skin rash, itching and hives (nettle rash or urticaria). In severe cases the signs include swelling of your tongue, lips and face, sudden difficulties in breathing and reduction in your blood pressure

See your doctor straight away if you have any of these side-effects.

Other side-effects:

Common (affects less than 1 in 10 people)

- Dry mouth

Uncommon (affects less than 1 in 100 people)

- Feeling weak, nervous, shaky or dizzy
- Cough
- Headache
- Feeling sick (nausea)
- Increased heart rate or uneven heart beats (palpitations)
- Increased blood pressure
- Voice problems ('dysphonia')
- Difficulty emptying your bladder (urinating)

Very rare (affects less than 1 in 10 000 people)

- Irregular heart rhythm
- Chest pain (due to heart problems such as angina). Tell your doctor or pharmacist if this occurs

The following side-effects can happen but the frequency is not known:

- Mood changes (mental disorder)
- Increased sweating
- Throat irritation, spasm in muscles around the voice box, tight chest
- Problems in motility of gut muscles, swelling of the lining of the mouth
- Decreased blood pressure
- Muscle cramps, muscle weakness and pain
- Being sick (vomiting)
- Allergic and hypersensitivity reactions
- Eye problems

You may also have unusually low levels of potassium in your blood (called 'hypokalaemia'). If this happens, your doctor will keep checking your potassium levels.

Not all side-effects reported for this medicine are included in this leaflet. Should you have any side-effects that bother you or do not go away, or if your general health worsens while using COMBIVENT U.D.V., or if you notice any side-effects that are not listed in this leaflet, please consult your doctor, pharmacist, or other health-care professional as soon as possible for advice.

If any of the liquid or mist accidentally gets into your eyes, you may have painful, stinging or red eyes, dilated (enlarged) pupils and blurred vision, and see colours or lights. If this happens, talk to your doctor for advice. If you have problems with your eyes at any time, talk to your doctor for advice.

6. STORING AND DISPOSING OF COMBIVENT U.D.V.

How do I store COMBIVENT U.D.V?

Store COMBIVENT U.D.V. below 30°C. Do not freeze. Do not use if the liquid is discoloured. Keep the vials in the original carton in order to protect from light.

Keep COMBIVENT U.D.V. and all medications out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the unit dose vials, on the pouch and on the carton. The expiry date refers to the last day of the month. Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF COMBIVENT U.D.V.

Strips of 10 unit dose vials enclosed in a laminated aluminium pouch, in cartons of 60 unit dose vials.

8. IDENTIFICATION OF COMBIVENT U.D.V.

Polyethylene unit dose vials containing a clear, colourless or almost colourless solution, free from suspended particles.

9. REGISTRATION NUMBER

30/10.2.1/0476

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

23 July 2010